

[Doc. No. 110]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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IN RE: BENICAR (OLMESARTAN)	:	Master Docket
	:	No. 15-2606 (RBK/JS)
PRODUCTS LIABILITY LITIGATION	:	
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O R D E R¹

This matter is before the Court on plaintiffs' Motion to Compel Discovery [Doc. No 110]; and the Court having received defendants' responses [Doc. Nos. 128, 129] and plaintiffs' reply [Doc. No. 137]; and the Court having held oral argument on September 30, 2015; and this Order intending to confirm the Court's rulings; and for all the reasons stated by the Court on the record; and good cause existing to issue this Order,

IT IS HEREBY ORDERED this 2nd day of October, 2015, that plaintiffs' Motion to Compel Discovery is GRANTED in part and DENIED in part; and it is further

ORDERED as follows:

1. Defendants shall search its ARGUS database using the additional 76 plus 20 search terms proposed by plaintiffs. By

¹ All references to documents in this Order shall also refer to responsive ESI.

October 10, 2015, defendants shall identify the number of responsive Adverse Event Reports ("AERs") that will be produced using the new search terms. All responsive AERs shall be produced by November 2, 2015.

2. The parties shall promptly meet and confer regarding plaintiffs' inquiries directed to defendants' AERs and ARGUS database. The Court will decide on the October 16, 2015 conference call whether plaintiffs will be granted leave to take a Fed. R. Civ. P. 30(b)(6) deposition on the topic.

3. Plaintiffs' request for the underlying source files for all AERs to be produced pursuant to paragraph 1 herein is DENIED. Nevertheless, having ruled that the source files are relevant and discoverable, the Court will order defendants to produce a representative number of source files. The determination of how many and which source files will be produced will await the production of the AERs in response to this Order and the satisfactory completion of paragraph 2 herein. When this is done plaintiffs shall identify which source files they request to be produced. Defendants shall respond in writing within one (1) week of the service of plaintiffs' request. After the parties exhaust their efforts to "meet and confer" plaintiffs may raise their disputes with the Court.

4. Defendants shall produce the following responsive documents that are held or possessed by Daiichi United States

and Daiichi Japan that concern or relate to Daiichi's subsidiaries located in the United Kingdom, Germany, Canada, France, Australia and Spain:

(1) olmesartan labels, package inserts, and instructions for use, including drafts, from 2008 to present.

(2) proposed or actual communications with regulators and internal discussions about:

a) labeling concerning gastrointestinal side effects of olmesartan, including the FDA safety announcement and the information added to the U.S. label in July 2013;

b) adverse event reports of gastrointestinal effects associated with olmesartan;

c) "dear doctor" letters or other notices to healthcare providers regarding gastrointestinal side effects of olmesartan, including any letters or notices regarding the FDA safety announcement and the information added to the United States label in July 2103.

(3) brochures, advertisements, internal reports, white papers, FAQs, and talking points that mention gastrointestinal side effects of olmesartan; and

(4) communications with researchers or academics about gastrointestinal side effects of olmesartan.

Defendants shall be prepared to discuss a reasonable time frame for the production of all responsive documents during the October 16, 2015 conference call.

5. With respect to plaintiffs' request for "qui tam" documents, by November 2, 2015, defendants shall produce the subpoena(s) served by the U.S. Department of Justice and the

enclosure letters and/or emails Daiichi served with the produced documents. This Order is entered without prejudice to plaintiffs' right to request more "qui tam" documents after the bellwether cases are identified.

6. By October 15, 2015, defendants shall produce for the Court's in camera review the 120 day Implementation Report referred to in Section V.A. (p.33) of Daiichi's Corporate Integrity Agreement ("CIA") and all Annual Reports (if any) produced pursuant to Section V.B. (p.35) of the CIA. The parties will be given an opportunity to address defendants' objections to production of these documents if the Court decides the documents contain relevant information.

s/Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge